DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 15, 2015

Togo Medikit Co., Ltd.
Izumi Maruo
Senior Consultant
4-1-17 Hongo
Bunkyo-ku, 113-0033 JA

Re: K141070
Trade/Device Name: Super Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DRE
Dated: December 8, 2014
Received: December 12, 2014

Dear Izumi Maruo,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141070

Device Name
SUPER SHEATH

Indications for Use *(Describe)*
The device is indicated for use in the introduction of diagnostic and interventional devices inserted into the peripheral and coronary vasculature.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

a. Owner/Company name, address

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c. Date prepared

April 18, 2014

d. Name of device

Trade Name:	SUPER SHEATH
Common Name:	Introducer, Catheter
Classification Name:	Catheter Introducer
Classification Regulation:	21 CFR 870.1340
Product Code:	DYB
Classification Panel:	Cardiovascular

e. Predicate devices

The SUPER SHEATH is substantially equivalent to the following legally marketed devices:

510(k):	k052557
Trade name:	Super Sheath Introducer Sheath and Introducer Sheath Sets, 4F-9F
Regulation Number:	21 CFR 870.1310
Product code:	DRE

510(k):	k121504
Trade name:	Super Sheath Introducer Sheath and Introducer Sheath Sets, 3.3F
Regulation Number:	21 CFR 870.1340
Product code:	DYB

Since the same name as predicate device is used, the new device under application is hereinafter called "the SUPER SHEATH (PROPOSED)" and the predicate devices are called "the SUPER SHEATH (k052557)" and "the 3.3F SUPER SHEATH (k121504)", respectively, for convenience of discussion in this application.

We are claiming substantial equivalence to product codes DRE and DYB.

f. Description of the device

Major components of the SUPER SHEATH (PROPOSED) are a sheath and a dilator. In addition, a guidewire is covered under this premarket notification. The guidewire is placed in the gudiewire case including inserter.

The sheath for the SUPER SHEATH (PROPOSED) is named as the SUPER SHEATH (PROPOSED) Introducer Sheath and is available in 4F- 9F diameters and in lengths ranging from 7 to 25 cm. Some types of sheaths have radiopaque markers. The SUPER SHEATH (PROPOSED) are provided sterile and are intended for one procedure use only.

The one-piece construction of the sheath shaft and hub allows smooth passage of concomitantly interventional medical devices. The sheath shaft and hub are made of Ethylene Tetrafluoro ethylene (ETFE) and polyamide.

The hubs, color-coded by French size, contain a hemostatic valve to minimize blood leakage during a procedure. A side tube equipped with a three-way stopcock is attached to the sheath hub. The side tube extension may be used for fluid and medication administration, as well as blood sampling. Some types of sheaths contain a marker band that is embedded in the shaft approximately 2.0 mm from the distal tip.

The dilator is an open tapered plastic tube with an integral luer hub for guidewire insertion. The dilator is inserted into the introducer sheath. The dilator is longer than the sheath with a rounded tapered distal tip. The dilator facilitates and supports the entry of the sheath into the patient's vasculature. Once the sheath is in place the dilator is removed. There are two different dilator distal tip sizes, 0.038" and 0.035" guidewire compatible. The 4F dilators are only available with a 0.035"guidewire lumen dilator. The 5-9F dilators are available with a

0.035" or 0.038" guidewire lumen. The 4-8F dilator tubes are made from Polypropylene (PP). The 9F dilator tubes are made of Fluorinated Ethylene Propylene (FEP). The dilator tubes are attached to the inner hub with a metal bush. The sheath hub and the dilator hub lock using a rotating motion.

The SUPER SHEATH (PROPOSED) has a polypropylene suture wing which is color coded by French size. The suture wing is a small projection near the hub with a hole in it for correct placement of the sheath using sutures.

The uncoated guidewire is made of a stainless steel coil wrapped tightly around an inner mandrel that tapers at the distal tip. The flexible tip is J-shaped available in diameters of 0.035" and 0.038". The guidewire, with inserter, is available in 45 cm and 80 cm lengths. The inserter is used strictly for guiding the guidewire into a cannula or introducer.

g. Indications for Use

Indication for Use
The device is indicated for use in the introduction of diagnostic and interventional devices inserted into the peripheral and coronary vasculature.

h. Statement of substantial equivalence
The main body of the SUPER SHEATH (PROPOSED) was essentially modified from the SUPER SHEATH (k052557). Thus, most of the characteristics of the SUPER SHEATH (PROPOSED) are similar to those of the SUPER SHEATH (k052557). Regarding packaging, the packaging materials and configuration are the same as the 3.3F SUPER SHEATH (k121504).

Comparison table of technological characteristics is as follows;

Comparison table of technological characteristics

Feature	SUPER SHEATH (PROPOSED)	SUPER SHEATH (k052557)	3.3F SUPER SHEATH (k121504)
Indications for Use	The device is indicated for use in the introduction of diagnostic and interventional devices inserted into the peripheral and coronary vasculature.	Introducer Sheaths and Introducer Sheath Sets are intended for use in the introduction of diagnostic and interventional devices into the human vasculature.	The Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets are indicated for use in the introduction of diagnostic and interventional devices inserted into the human vasculature of adult and pediatric patients of all ages.
Regulation	870.1340	870.1310	870.1340

Number					
FDA Product Code	DYB		DRE		DYB
Prescription/OTC Use	Prescription		Prescription		Prescription
Single-use/Reusable	Single-use		Single-use		Single-use
Sheath					
French Sizes Available	4F- 9F		4F- 9F		3.3F
Effective Length	7 cm – 25 cm		7 cm – 25 cm		5 cm – 7 cm
Sheath Shaft Inner Diameter (ID)	1.58 mm – 3.23 mm		1.58 mm – 3.23 mm		1.30 mm
Sheath Shaft Outer Diameter (OD)	1.98 mm – 3.69 mm		1.98 mm – 3.69 mm		1.70 mm
Sheath Shaft Materials	Ethylene tetrafluoro ethylene (Neoflon® ETFE EP-526):90% Barium Sulfate: 10%		Ethylene tetrafluoro ethylene (Neoflon® ETFE EP-522):85% Barium Sulfate: 15%		Ethylene tetrafluoro ethylene (Neoflon® ETFE EP-522):85% Barium Sulfate: 15%
Cover Tube Material	Ethylene tetrafluoro ethylene (Neoflon® ETFE EP-526)		Ethylene tetrafluoro ethylene (Neoflon® ETFE EP-522)		Not Applicable
Radiopaque Marker	Tantalum		Tantalum		Not Applicable
Dilator					
Dilator Tube Materials	4F −8F: Polypropylene 9F: Fluorinated ethylene propylene		4F −8F: Polypropylene 9F: Fluorinated ethylene propylene		Polypropylene
Dilator Tube Inner Diameter (ID)	4F-8F	0.92 mm – 1.00 mm (0.035” *)	4F-8F	0.92 mm – 1.00 mm (0.035” *)	0.65 mm – 0.75 mm
		1.02 mm– 1.10 mm (0.038” *)		1.02 mm– 1.10 mm (0.038” *)	
	9F	0.95 mm – 1.05 mm (0.035” *)	9F	0.95 mm – 1.05 mm (0.035” *)	
		1.05 mm– 1.15 mm (0.038” *)		1.05 mm– 1.15 mm (0.038” *)	

Dilator Tube Outer Diameter (OD)	1.38 mm – 3.09 mm	1.38 mm – 3.09 mm	1.23 mm
Dilator Tube Effective Length	13 cm – 31 cm (130 mm – 310 mm)	13 cm – 31 cm (130 mm – 310 mm)	10.5 cm to 12.5 cm (105 mm – 125 mm)
Dilator Distal Tip	0.035”* 0.038” *	0.035” * 0.038” *	0.018” 0.021” 0.025”
Guidewire and Inserter			
Guidewire Tip Shape	J-tip	J-tip	Straight type
Outer Diameter	0.035”, 0.038”	0.035”, 0.038”	0.025”
Inserter	Available	Available	Available
Sterilization and Shelf-life			
Sterilization method	Ethylene oxide	Ethylene oxide	Ethylene oxide
Sterile Package	Pouch	Blister package	Pouch
Shelf-Life	Two (2) years	Three (3) years	Three (3) years

Note*: There are two different dilator distal tip sizes, 0.038" and 0.035" guidewire compatible. Note that the 4F dilators are only available with a 0.035"guidewire lumen dilator. The 5-9F dilators are available with a 0.035" or 0.038" guidewire lumen.

SUPER SHEATH (k052557) referenced regulation number 870.1310 and product code DRE. However 3.3F SUPER SHEATH (k121504) for additional sizes utilized regulation number 870.1340 and product code DYB, which are referenced by the current submission. Citation of 870.1340 /DYB is presumably the most current regulatory practice as evidenced by 3.3F SUPER SHEATH (k121504).

Regarding the main body of the SUPER SHEATH (PROPOSED), major components are a sheath and a dilator. In addition, a guidewire is covered under this premarket notification. The guidewire is placed in the Gudiewire case including inserter. The only difference from the SUPER SHEATH (k052557) is the modifications of material change of the sheath shaft.

In order to evaluate any effects of the above changes on safety and effectiveness for the main body, biocompatibility testing and bench testing including shelf-life testing were performed.-Biocompatibility testing demonstrated that the SUPER SHEATH (PROPOSED) does

not raise any biocompatibility concern. Bench testing including shelf-life testing demonstrated that the performance of the main body of the SUPER SHEATH (PROPOSED) was comparable to that of the SUPER SHEATH (k052557).

Regarding packaging of the SUPER SHEATH (PROPOSED), packaging integrity test and sterility test demonstrates the packaging works as a sterile barrier for the SUPER SHEATH (PROPOSED) and is substantial equivalent to the packaging of the 3.3F SUPER SHEATH (k121504).

Based on above, we concluded that the modification did not raise any new safety or effectiveness concerns compared to the SUPER SHEATH (k052557) for main body and the 3.3F SUPER SHEATH (k121504) for packaging.

i. Bench Testing

The following bench tests were performed to ensure the safety and effectiveness of the SUPER SHEATH (PROPOSED), verify conformity to the international standards and in-house requirements, and demonstrate substantial equivalence to the SUPER SHEATH (k052557).

- Sheath Shaft Tensile Test
- Sheath Kink Test
- Sheath Hub to Shaft Tensile Test
- Valve Integrity of Sheath
- Sheath Lubricity Test
- Sheath Radiopacity Test
- Cover Tube Durability Test
- Hemostatic Valve Integrity/Sheath Pressure Test
- Sheath/Dilator Corrosion Resistance Test
- Dilator Shaft Tensile Test
- Dilator Hub to Shaft Tensile Test
- Guidewire Tensile Test
- Guidewire Combined Load Test
- Guidewire Torqueability Test
- Guidewire Radiopacity Test
- Guidewire Corrosion Resistance Test

j. Biocompatibility Testing

We performed following biocompatibility tests because of material change of the sheath shaft;

- Cytotoxicity
- Intracutaneous reactivity
- Sensitization
- Acute Systemic Toxicity
- Hemocompatibility
- Pyrogen test
- LAL test

In the biocompatibility testing reports, no biocompatibility concern was raised.

k. Conclusion

Based on the above discussion and enclosed sections regarding substantial equivalence to predicate devices, TOGO MEDIKIT concludes that the SUPER SHEATH (PROPOSED) is substantially equivalent to the SUPER SHEATH (k052557) and the 3.3F SUPER SHEATH (k121504) , and the SUPER SHEATH (PROPOSED) does not raise any new questions regarding safety or effectiveness.